IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next Kin of Richard Smith, Deceased,	)	
Plaintiff,	)	Civil No. 3:05-0444
	)	Judge Aleta A. Trauger
v.	)	(Dist. Of MA No. 1:05-cv-11515PBS)
PFIZER, INC., *et al.*,	)	
Defendants.	)	

DEFENDANTS' OBJECTIONS TO THE PROPOSED STATEMENT OF PLAINTIFF'S EXPERT CHERYL BLUME, PH.D.

Pursuant to the Court's Scheduling Order of April 30, 2010, as amended orally due to flooding in Nashville, Defendants, Pfizer Inc and Warner-Lambert Company LLC (collectively, "Defendants" or "Pfizer") herein submit their objections to the expert witness statements proffered by Plaintiff's expert, Cheryl Blume, Ph.D. These objections are in addition to, and without waiving, any applicable objections made in connection with Defendants' motions in limine that were filed and ruled upon by the Court. Defendants Pfizer Inc. and Warner-Lambert Company LLC respectfully submit the following Memorandum in Support of Defendants' Objections to the Statement of Plaintiff's Expert Cheryl Blume, Ph.D. Attached as **Exhibit A** to this Memorandum is a table setting forth Defendants' specific objections to Dr. Blume's testimony. Attached as **Exhibit B** to this Memorandum is the deposition testimony of Dr. Blume cited in this Memorandum and Exhibit A to this Memorandum.

I. DR. BLUME'S OPINIONS CONTRARY TO TENNESSEE'S LEARNED INTERMEDIARY RULE SHOULD BE EXCLUDED

Dr. Blume makes several references to Defendants' supposed failure to provide adequate warnings to "patients." Any alleged failure to provide warnings to "patients" or to "Mr. Smith" is not relevant to any legal issues because it is well settled in Tennessee that under the "learned intermediary" doctrine, Defendants have a duty to provide an adequate warning to the physician, not to the patient. *See Pittman v. Upjohn Co.*, 890 S.W. 2d 425 (Tenn. 1994). Furthermore, any such testimony would only serve to mislead and confuse the jury, would be wasteful, and unduly prejudicial.

The following references to Defendants' alleged failure to provide an adequate warning to "patients," to "Mr. Smith," or to any individual who is not a prescribing health care provider should be excluded:

¶ 2: "I have been asked to investigate and provide opinions about whether Warner Lambert and Pfizer failed to warn doctors and patients…"

¶ 3: "I cannot stress enough that the Defendants did not need to have definitive proof that Neurontin causes suicidal behavior before warning doctors and patients about it.

¶ 13: "Patients like Mr. Smith were not warned about the potential for suicide-related side effects with Neurontin."

¶ 18: "In this case with Neurontin, let me summarize for some of the 'signals' or red flags Defendants knew about but failed to warn doctors and patients."

¶ 22: "Yet this very critical safety information was withheld from doctors and patients."

¶ 29: "It summarizes safety related to suicide events and which should have caused Defendants to warn doctors and patients."

¶ 38: "The safety signal for Neurontin should have resulted in a warning by Defendants to doctors and patients."

¶ 43: "This was a safety signal that should have spurred Defendants to act and warn doctors and patients."

¶ 45: "Had they looked in their own clinical trial data and what the FDA had said when the drug was first approved, they would have realized that there was a serious risk of suicidal behavior that was not adequately disclosed to doctors and patients."

¶ 46: "This was simply not good enough in terms of adequately providing doctors and patients with directions to use Neurontin safely…"

¶ 50: "Well, 'directions for use' include informing the doctors and patients about how to use Neurontin safely and Defendants did not have adequate instructions for use regarding risks of suicide related events. So, patients and doctors were not informed to use Neurontin safely."

¶ 51: "As I explained earlier, the drug company did not need definitive proof that Neurontin causes suicidality to enhance their labeling and warn doctors and patients about the potential for suicide behavior with Neurontin."

¶ 62: "Defendants failure to include a prominent, enhanced warning related to suicide events means that doctors and patients did not have adequate risk-benefit information about Neurontin."

II. DR. BLUME'S IMPROPER SUMMARY AND CHARACTERIZATION OF DOCUMENTS AND EVIDENCE SHOULD BE EXCLUDED

Dr. Blume's testimony is filled with her characterizations of documents and evidence devoid of any scientific analysis. Dr. Blume offers her "spin" on numerous exhibits, and purports to testify as to the significance of evidence, but does not provide any analytical support for her opinions. Indeed, much of Dr. Blume's expert witness statements reads like a closing argument and merely consists of her "recite evidence, and jump to a conclusion" methodology, without any true analysis of regulatory requirements or how such requirements are commonly applied in the industry.

Similar testimony by Dr. Blume was excluded by a federal court in Minnesota in another pharmaceutical case last year. *In re Viagra Prods. Liab. Litig*, 658 F. Supp. 2d 950, 967 (D. Minn. 2009). This case and other relevant federal authorities excluding similar "regulatory experts" in drug product liability cases is discussed below.

Such "historical commentary of what happened" should be excluded because it does not assist the trier of fact. *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 538 (S.D.N.Y. 2004); *see In re Trasylol Products Liab. Litig.*, Case No. 08-MD-01928 (S.D. Fla. Apr. 27, 2010) (excluding regulatory expert who did not provide regulatory analysis to support her opinions, but rather relied on her own interpretation of internal corporate documents); *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009); *In re Viagra Prods. Liab. Litig*, 658 F. Supp. 2d 950, 967 (D. Minn. 2009); *In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871 (E.D. Ark. 2008). Dr. Blume is a perfect example of what the *Rezulin* Court found improper:

> A practice … has become fashionable among some well-financed litigants – the engagement of "expert" witnesses whose intended role is more to argue the client's cause from the witness stand than to bring to the fact-finder specialized knowledge or expertise that would be helpful in resolving the issues of fact presented by the lawsuit. These "experts" . . . lend their credentials and reputations to the party who calls them without bringing much if any relevant knowledge to bear on the facts actually at issue.

Rezulin, 309 F. Supp. 2d at 538.

Indeed, an expert should "not be permitted to merely read, selectively quote from, or 'regurgitate' the evidence." *Fosamax*, 645 F. Supp. 2d at 192 (rejecting expert testimony that characterized corporate conduct in a conclusory fashion, summarized and selectively quoted from internal documents and regulatory filings, and theorized about a defendant's intent, motive, and knowledge); *see also In re Prempro Prods. Liab. Litig.*, 554 F. Supp. at 879, *aff'd*, 586 F.3d 547, 571 (8th Cir. 2009) (upholding trial court's order striking expert where regulatory expert consisted of a "brief overview of some federal regulations, followed by a discussion of specific exhibits, largely devoid of regulatory analysis").

In *Prempro*, the plaintiff proffered a regulatory expert who was supposed to testify about the standard of care required of pharmaceutical companies in the context of FDA regulations.

Prempro, 554 F. Supp. 2d at 878. At trial the expert cited only three FDA regulations (Dr. Blume's statement cites only one regulation (Statement, ¶ 15)), and then summarized selected documents to support her opinion that the defendant violated FDA rules. *Id*. at 879. The District Court struck the expert's testimony, rejecting the plaintiff's argument that the expert was needed to distill volumes of documents. *Id*. at 886. The Court found that the expert did "nothing, or little more, than read exhibits" and did "no more than counsel for plaintiff did in argument, i.e., propound a particular interpretation of defendant's conduct." *Id.* at 886-87 (citing *In re Rezulin*, 309 F. Supp. 2d at 551). The Court cautioned that judges should "not be deceived by the assertions of experts who offer credentials rather than analysis." *Id*. at 887 (citations omitted). "Having an expert witness simply summarize a document (which is just as easily summarized by a jury) with a tilt favoring a litigant, without more, does not amount to expert testimony." *Id*. at 887.

Selective spinning of the evidence does not assist the tier of fact: an understanding of corporate documents requires no particular expertise, and is based on no identifiable expert methodology. *Fosamax*, 645 F.Supp.2d at 192. Thus, if a narrative derived from internal documents is admissible at all, it must be presented to the jury directly, not via a witness serving as a plaintiff's mouthpiece. *Id*.

In fact, as noted, Blume's narrative tactic, specifically summarizing regulatory history and documents concerning regulatory activities, has been excluded previously by Courts as recently as last year:

> Dr. Blume devotes a significant portion of her opinion to summarizing the regulatory history…The Court finds little to distinguish Dr. Blume's factual history of Viagra from the histories that were excluded in *Rezulin* [*In re Rezulin Prod. Liability Litig*., 309 F. Supp. 2d 531 (S.D.N.Y.2004)] and *Fisher* [*Fisher v. Ciba Specialty Chems. Corp*., 238 F.R.D. 273 (S.D.Ala.2006)]. Although, as Plaintiffs argue, Dr. Blume no doubt used her expertise to wade through the

> multitude of possibly relevant documents, "[t]he vast majority of [Dr. Blume's] report simply summarizes and states her advocacy-based interpretation of documents in the record concerning" regulatory activity related to Viagra. *Fisher*, 238 F.R.D. at 281. The question is not whether the jury could review all 700,000 pages of material and recreate the history that Dr. Blume provided in her report, but whether the jury could interpret the documents that Dr. Blume highlights in her report without the assistance of an expert. Dr. Blume's chronology does not appear to benefit from her regulatory expertise in any way, nor does her chronology appear to be "any more or less persuasive than that of a layperson." *Id*. Accordingly, Dr. Blume's chronology of Viagra regulatory events must be excluded.

Viagra, 658 F. Supp. 2d at 967 (D. Minn. 2009) (emphasis added).

In addition, Dr. Blume improperly offers her personal views on Defendants' conduct. It is well settled that an expert witness is not permitted to offer her personal views on a party's conduct, nor is an expert allowed to express those views in legal conclusions. *See Estate of Sowell v. United States*, 198 F.3d 169, 171 (5th Cir 1999) (affirming exclusion testimony that the Estate was "acting reasonably" because "[w]hether the Estate was 'acting reasonably' was, for all practical purposes the only issue for the jury"); *Askanase v. Fatjo*, 130 F.3d 657, 665 (5th Cir. 1997) (affirming exclusion of expert testimony about whether officers and directors had "breached their fiduciary duties"); *Smogor v. Enke*, 874 F.2d 295 (5th Cir. 1989) (affirming exclusion of expert testimony on ultimate issues of "negligence, proximate causation, and gross negligence"); *In re Baycol Products Litig.*, 532 F. Supp. 2d 1029, 1054 (D. Minn. 2007) (ruling that FDA expert "may not infuse his personal views as to whether Bayer acted ethically, irresponsibly or recklessly"); *In re Rezulin Products Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004) (excluding opinion that the defendant's conduct "constituted 'negligence' or 'something more serious'" because it is "outside the bounds of expert testimony" and "impermissibly embraces a legal conclusion").

The following are a few of the more glaring examples:

¶ 3: "I cannot stress enough that the Defendants did not need to have definitive proof that Neurontin causes suicidal behavior before warning doctors and patients about it.

¶ 12: "Unfortunately, these clinical trials are often done with small numbers of people for short periods of time."

¶ 13: "Even if the Defendants try to claim that they did not promote the drug improperly, they certainly knew that most of the people who were using the drug were using it for off-label uses.

¶ 13: "Doing this placed the public at risk of being harmed, and Mr. Smith is the victim of the Defendants' action."

¶ 14: "Based on my review of documents, Pfizer wasn't careful and people like Mr. Smith died."

¶ 15: "Essentially, Defendants did too little, too late."

¶ 20: "In my area, these kind of events are so rare, that even one single event like this one is big deal."

¶ 23: "This document proves Defendants admit that Neurontin affects neurotransmitters in the brain since the 1980s."

¶ 23: "This is important because these effects could contribute to suicidal behavior."

¶ 23: "Otherwise it was 'don't ask, don't tell' and business as usual."

¶ 24: This entire paragraph is simply Dr. Blume excerpting and commenting on the deposition of a company witness without even a pretense of regulatory analysis.

¶ 25: "Again this is important to know…"

¶ 27: "What this means is that the Neurontin in certain patients made their behavioral problems worse."

¶ 27: "As I mentioned earlier, Dr. Trimble is now an expert for the Plaintiffs in this case."

¶ 28: "For an industry person concerned with pharmacovigilance events and drug safety, this chart is very settling."

¶ 29: "Most critical is that despite both of these charts, the labeling wasn't changed and off-label use was skyrocketing."

¶ 31: "In a document from March 2001, the Defendants admitted that since they didn't have an approval for pain, they didn't really know if it was safe."

¶ 37: "This exhibit is important because it shows the Defendants knew it was feasible to look specifically at suicide related events."

¶ 37: "This shows that the company agrees that it was appropriate to combine the suicide related terms, just as I did a few moments ago."

¶ 42: "What's also important about this chart…"

¶ 46: "Now, Defendants may say the words "suicidal" or "suicide gesture" were included in the premarketing labeling events for Neurontin, but this was only in their laundry list of side effects. This was simply not good enough in terms of adequately providing doctors and patients with directions to use Neurontin safely, particularly in light of the postmarketing evidence I have shown you today.

¶ 47: "There was some language that the company buried in the label that said "suicidal" and 'suicide gesture'."

¶ 47: "There is no way that the label could have been telling doctors of the risk of actual "completed" suicide if the company was telling the FDA it wasn't in the label in the first place."

¶ 48: "So, don't believe the defendants if they claim that they ever warned for "suicide" during Mr. Smith's life."

¶ 51: "The Defendants may tell you that until the FDA in 2008 warned doctors about risks of suicidality, they had no idea about Neurontin and suicide."

¶ 51: "Well, the facts that I have shown you today clearly indicate that their argument is not true."

III. DR. BLUME'S OPINIONS BASED ON A HEIGHTENED DUTY TO WARN OR MONITOR ARE UNSUPPORTED AND SHOULD BE EXCLUDED

A pervasive theme throughout Dr. Blume's testimony is her opinion that Defendants had a heightened duty to monitor and warn about potential safety issues related to patients using Neurontin for off-label indications. Dr. Blume repeatedly refers to these patients as "vulnerable" although she is not qualified to assess anyone's medical condition; nor does she offer an expert opinion as to how her statements are relevant to what these defendants did or did not do in this case. More importantly, there is no scientific evidence to support the premise of this opinion:

that adverse events effects are somehow dependent on why Neurontin was prescribed. Indeed, Plaintiff's general causation theory relies upon a May 2008 FDA meta-analysis that concludes, "There is no obvious subgroup of patients to which the increased risk is specifically attributed. The increased risk was seen in almost all subgroups, although epileptic and Non-North American patients may have higher relative risks." (Defendant's Trial Ex. 7247) Thus, the only "subgroup" that "may" have a higher relative risk are epileptic patients who were using the medication for an FDA-approved indication. Dr. Blume simply has no reliable scientific evidence to support her opinion that Defendants should have implemented further monitoring procedures specifically for off-label patients because these patients were at greater risks.

Moreover, although Dr. Blume cites 21 C.F.R. § 314.80 (the only regulation she mentions in her entire witness statement (Statement, ¶ 15)), she provides no expert analysis and cites not language from the regulation to support her unscientific claim that Defendants were required by this regulation, or any other regulation, to implement a two-tiered monitoring system based upon "vulnerability".

The following paragraphs should be excluded from Dr. Blume's witness statement:

¶ 12: "Also let me be clear: just because FDA has found the drug's benefits outweighed the risk for uses like epilepsy and shingles pain, there is no proof that FDA ever decided the drug was safe for anything else."

¶ 13: "Even if the Defendants try to claim that they did not promote the drug improperly, they certainly knew that most of the people who were using the drug were using it for off-label uses. Since Neurontin did not have FDA approvals for these uses, the Defendants didn't know if Neurontin was safe or even effective for their unproven uses."

¶ 13: "Since Neurontin did not have FDA approval for these uses, the Defendants didn't know if Neurontin was safe or even effective for their unapproved uses."

¶ 14: "It is my opinion that when a drug company knows that most of the people using their drug are using it for "off-label" uses, where safety and effectiveness has not been proven, then the company needs to be even more careful."

¶ 22: "Even though the Defendants were fully aware that the drug could have these effects, the company marketed the drug 'off label' to the very individuals who were most vulnerable. Yet this very critical safety information was withheld from doctors and patients. "

¶ 23: "For doctors treating vulnerable patients with psychiatric and pain conditions, this is critical information that was not in the label."

¶ 31: "In a document from March 2001, the Defendants admitted that since they didn't have an approval for pain, they didn't really know if it was safe."

IV. DR. BLUME'S OPINIONS BASED ON SUBSEQUENT REMEDIAL MEASURES SHOULD BE EXCLUDED

Dr. Blume proposes to support her opinion that Defendants' safety monitoring system was inadequate in 2004 by relying on a "Gabapentin Data Capture Aid" developed by Defendants in 2006. This testimony is plainly inadmissible as a subsequent remedial measure under Fed. Evid. Rule 407. *See Werner v. Upjohn Co*., 628 F.2d 848 (4th Cir. 1980) (reversing jury verdict because the plaintiff was allowed to present evidence of subsequent labeling change even though trial court had given two limiting instructions). Dr. Blume leaves no doubt as to her purpose in testifying about this subsequent addition in Defendants' safety monitoring documentation, "My point in showing you this document is that Defendants should have and could have come up with this plan years before Mr. Smith died." (Statement, ¶ 37.) Of course, Defendants have never contended that such a plan was not feasible, only that it was not necessary at the time of Mr. Smith's death to evaluate the safety of Neurontin. *See* Fed. R. Evid. 407 ("This rule does not require the exclusion of evidence of subsequent measures when offered for another purpose, such as …proving feasibility of precautionary measures, if converted") (emphasis added).

Any testimony by Dr. Blume as to subsequent safety monitoring procedures should be excluded, including the following paragraphs:

¶ 15: "The Defendants, as I will explain later, did implement a system for collecting information about suicidal behavior, but only after Mr. Smith died. There is no reason that this could not have been done long before his death. Essentially, Defendants did too little, too late."

¶ 37: Entire paragraph devoted to discussing 2006 "Gabapentin Data Capture Aid."

V. DR. BLUME IS NOT QUALIFIED TO OFFER OPINIONS ABOUT NEURONTIN'S "MECHANISM OF ACTION"

Dr. Blume purports to offer opinions regarding the effects of Neurontin on chemicals in the brain (called neurotransmitters), and how these chemical effects may influence a patient's mood and behavior. This subject area is known as Neurontin's "mechanism of action" and Dr. Blume simply does not have the necessary expertise to offer any opinions on this issue.

"Before a district court may allow a witness to testify as an expert, it must be assured that the proffered witness is qualified to testify by virtue of his 'knowledge, skill, experience, training, or education.'" *U.S. v. Cooks*, 589 F.3d 173, 179 (5th Cir. 2009) (quoting Fed. R. Evid. 702). "A district court should refuse to allow an expert witness to testify if it finds that the witness is not qualified to testify in a particular field or on a given subject." *Id*. (citing *Wilson v. Woods*, 163 F.3d 935, 937 (5th Cir. 1999)).

Indeed, in her deposition last week Dr. Blume all but conceded her lack of expertise when asked her opinion on a recent scientific article, stating, "[o]f course there's other people who are going to be directly speaking to the mechanism of action." Deposition of Dr. C. Blume, May 7, 2010, 33:13-16. Dr. Blume's claimed reliance on more qualified experts to testify as to Neurontin's mechanism of action is fully consistent with her prior deposition testimony. *See* Deposition of Dr. C. Blume, Nov. 13, 2007, 571:12-572:5 ("Are you going to express opinions concerning the mechanism of action…?" "I don't think I'll be offering that specific opinion because there are other –there are other people who are going to be doing that.")

Dr. Blume's professed lack of expertise is not surprising; she is not a neurologist, not a medical doctor, not a neurobiologist, and not a neuropharmacologist. In other words, Dr. Blume does not have the requisite qualifications to offer opinions on Neurontin's mechanism of action. Her testimony on this subject will not "assist the trier of fact" and should be excluded as inadmissible under Fed. R. Evid. 702.

In addition, as acknowledged by Dr. Blume, any testimony by her as to Neurontin's mechanism of action will be duplicative and should also be excluded on this independent ground. *See* Fed. R. Evid. 403.

The following paragraphs should be excluded from Dr. Blume's witness statement:

¶ 23: Entire paragraph discussing mechanism of action.

¶ 24: Paragraph mischaracterizing deposition testimony of company on mechanism of action, expressing her agreement with this mischaracterization, and offering this agreement as support for her unqualified opinion.

¶ 25: Discussing mechanism of action.

VI. DR. BLUME'S OPINIONS THAT RELY ON DATA SUPPLIED BY PLAINTIFF'S COUNSEL, AND ON DATA WAS NOT DISCLOSED IN HER REPORT SHOULD BE EXCLUDED

Dr. Blume bases her opinion that Defendants failed to adequately monitor safety data on an analysis of adverse event reports conducted by Plaintiff's counsel, Mr. Keith Altman. (Statement, ¶¶ 38-41.) Dr. Blume proposes to show the jury a chart, "PRR Over Time Suicidal and Self-Injurious Behavior (HLT)" (PRR Chart) and tell the jury that the information on the PRR Chart "show[s] signals that the company, if it is doing its job, will look for and investigate." (*Id*. at ¶ 41.) The problem is that the PRR Chart, and all the information included on the PRR Chart, was supplied to Dr. Blume by Plaintiff's counsel.

While experts may rely upon data supplied by others in appropriate circumstances, they must undertake an independent investigation to verify the accuracy of the data. For example, in *American Key Corp. v. Cole National Corp.*, 762 F.2d 1569, 1580 (11th Cir. 1985), the court discredited testimony from an expert who based his opinion on facts from a layman while failing to independently "verify the 'facts' submitted to him." *See also SMS Sys. Maint. Servs., Inc. v. Digital Equip. Corp.*, 188 F.3d 11, 25 (1st Cir. 1999) (stating that "an expert must vouchsafe the reliability of the data on which he relies and explain how the cumulation of that data was consistent with standards of the expert's profession."). This need for an independent investigation is especially pertinent where, as here, the information was supplied by an interested party. *See*, *e.g.*, *Ellipsis, Inc. v. Color Works, Inc.*, 428 F. Supp. 2d 752, 761 (W.D. Tenn. 2006) (excluding testimony as unreliable where, among other flaws, the expert "relied exclusively on data provided by" plaintiff).

Dr. Blume has not independently verified, tested, audited, or validated the data she was given by Mr. Altman. (*See* Blume Depo., Nov. 12, 2007, 92:1-4, 97:21-98:2.) Nor has she validated the PRR Chart that includes this data and appears at paragraph 39 of her witness statement. (*Id.* at 102:25-103:7.) Even more troubling is Dr. Blume's admission that she is not capable of independently validating these data, yet she plans to present it to the jury as valid and reliable scientific evidence. (*Id*. at 69:3-10).

Moreover, because Dr. Blume has not—and cannot—independently validate the data she received from Plaintiff's counsel, she cannot assure herself, or the jury, that this data is reliable, pragraphs 38 through 41 should be excluded from her witness statement.

In addition to the PRR Chart, Dr. Blume plans to show the jury two other charts, "Altman-B" and "Altman-D" from Plaintiff's Ex. 4159 (Statement, ¶¶ 43-45 (citing Ex. 4159)).

These documents were not disclosed in her October 22, 2007 Expert Report, but rather were exhibits to a Declaration of Mr. Altman filed in April, 2008—months after Dr Blume's expert report was served and her depositions were taken in this case. These documents from Ex. 4159 and the related testimony should be excluded pursuant to Fed. R Civ. Pro 26(a)(2)(B) and 37(c)(1), as well as FRE 702 and 802.

Plaintiffs should not be allowed to present Ex. 4159 as part of Dr. Blume's testimony, nor should Dr. Blume be permitted to offer any opinions based on this Exhibit because it was not part of her Expert Report. Paragraphs 43 through 45 should be excluded from Dr. Blume's witness statement.

Dated: May 12, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this the 12th day of May 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing document are being served via the Court's CM/ECF system on the following:

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